

## **EXHIBIT A**

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF IOWA  
CENTRAL DIVISION

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KEMIN FOODS, L.C., and THE CATHOLIC  
UNIVERSITY OF AMERICA,

Plaintiffs,

vs.

PIGMENTOS VEGETALES DEL CENTRO  
S.A. DE C.V.,

Defendant.

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No. 4:02-cv-40327

**ORDER ON PLAINTIFF'S  
MOTION TO APPLY**

**35 U.S.C. § 295**

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35 U.S.C. § 295**

This matter is before the Court on Plaintiff's Motion to Apply 35 U.S.C. § 295 (Clerk's No. 171). Plaintiff moves the Court to apply section 295 to establish a presumption that Defendant's purified lutein product is made by Kemin's patented process. Attorneys for Plaintiff are Susan K. Knoll, Scott W. Clark, and Ed Mansfield; attorneys for Defendant are G. Brian Pingel, Michael A. Dee, and Camille L. Urban. Oral argument on this motion was held on August 19, 2004. The motion is now fully submitted and ready for ruling.

**PROCEDURAL HISTORY**

The Plaintiffs, Kemin Foods, L.C. ("Kemin") and The Catholic University of America, filed an infringement action against the Defendant, Pigmentos Vegetales del Centro S.A. de C.V. ("PIVEG"), on July 9, 2002. The lawsuit alleges infringement of two patents held by Kemin, U.S. Patent Nos. 5,382,714 ("the '714 patent") and 5,648,564

(“the ‘564 patent”), by PIVEG. In turn, PIVEG has alleged several counterclaims against Kemin relating to the patents-in-issue.

Trial is scheduled to begin September 13, 2004, and is scheduled to last for approximately ten days. On January 13, 2004, the Court issued an Order on Claim Construction (Clerk’s No. 120),<sup>1</sup> construing the relevant claims of both the ‘714 and ‘564 patents. The Court amended this order on May 18, 2004, when it granted PIVEG’s motion to alter or amend order on claim construction in light of the Federal Circuit reversal of the preliminary injunction imposed by this Court (Clerk’s No. 163).<sup>2</sup> The parties have since proceeded according to the scheduling order, and there are currently dispositive motions pending before the Court.<sup>3</sup>

#### **BACKGROUND FACTS<sup>4</sup>**

As previously noted, Kemin filed this action asserting infringement of two patents, a product patent (the ‘714 patent) and a process patent (the ‘564 patent). Relevant to the present motion, Kemin asserts, *inter alia*, that PIVEG’s process for the production of

<sup>1</sup> See Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V., 301 F. Supp. 2d 970 (S.D. Iowa 2004) [hereinafter “Kemin I”].

<sup>2</sup> See Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V., 319 F. Supp. 2d 939, 71 U.S.P.Q. 1637 (S.D. Iowa 2004).

<sup>3</sup> Defendant’s Motion for Summary Judgment (Clerk’s No. 164) and Plaintiff’s Motion to Strike (Clerk’s No. 176) will be addressed in a separate order.

<sup>4</sup> The Court is well aware of the background facts in this case and will not repeat them here. Instead, this section will set forth those facts relevant to the Kemin’s pending motion to apply the section 295 presumption.

purified lutein infringes Kemin's patented '564 process. PIVEG's process for producing lutein takes place in its manufacturing facilities located in Celaya, Mexico.

Discovery has been ongoing since October of 2002, and fact discovery closed March 22, 2004. The only document that PIVEG has produced related to its process for producing lutein is a two-page document entitled "PIVEG PROCESS – Isolation and purification of xanthophyll crystals" ("PIVEG's process document"). This document was prepared at the behest of PIVEG's counsel during the course of this litigation. PIVEG has no other nonprivileged documents describing its process for producing lutein. Indeed, it is apparently company policy, based on specific instructions from company officials, to not keep any documented records of the process.

Based on the lack of documentation, Kemin requested and was permitted by PIVEG to conduct a limited inspection of PIVEG's Celaya, Mexico, manufacturing facility. This inspection took place on July 24, 2003 [hereinafter "first inspection"], and included Kemin's outside counsel and technical experts retained by Kemin. At the first inspection, a significant portion of PIVEG's process was not operational, and that which was functioning was not operating under normal conditions.<sup>5</sup> Kemin asserts these conditions rendered many of the observations of the first inspection useless. Kemin was

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<sup>5</sup> Kemin does note that it was made aware prior to the inspection that a portion of the lutein purification process would not be functional during the visit. Kemin states it decided to go ahead with the inspection in light of the impending August 28, 2003, deadline for expert reports as well as the numerous difficulties encountered in scheduling the visit.

unable to observe a complete product cycle. In addition, Kemin was further unable to obtain samples at the pertinent steps of PIVEG's production process, and those samples that were obtained were not to specification and therefore had little, if any, value.

As a result of the marginal value of the first inspection, Kemin sought a second inspection of PIVEG's lutein purification process. This became the subject of a motion to compel filed August 26, 2003.<sup>6</sup> Following resolution of these issues, Kemin undertook another inspection of the production facility in Celaya, Mexico, on November 14-15, 2003 [hereinafter "second inspection"]. The second inspection was led by certain PIVEG personnel, including Mr. Robert Espinoza and Mr. Jose Pichardo. For Kemin, the inspection was conducted by experts Dr. Giorgio Carta and Dr. Reyna Vidal, a videographer, and counsel for Kemin.

Prior to the planned demonstration, the parties agreed that two runs would be conducted: the primary process run of PIVEG's process, and a second process run to allow for sampling after the first step of PIVEG's purported process. This secondary run was required because, according to PIVEG, the reactors used by PIVEG were not equipped

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<sup>6</sup> While both parties were able to agree to a second inspection in principle, the parties were unable to reach an agreement regarding certain essential points, including the use of photographic, video, or similar devices, and the extent of the process to be viewed. The Court held a hearing on these issues on September 17, 2003, and entered an order dictating terms of the second inspection. Pursuant to the Court's order, this inspection was to take place on October 13-14, 2003, though the actual visit did not take place until mid-November 2003 due to the unavailability of Mr. Espinoza.

with the means to withdraw samples under vacuum, and the second run would be vented to the atmosphere at the end of the reaction time and opened to allow sampling.

Two additional runs were also conducted by PIVEG during the second inspection. Kemin alleges these were unplanned and unexpected and made on PIVEG's own initiative. Kemin's expert, Dr. Carta, believed these runs were conducted after PIVEG discovered the extent of saponification<sup>7</sup> was low in the second run, and then again in the third run. The final two runs were only partially observed by Kemin, and no starting materials were collected.

Kemin alleges the ability of its inspection team to observe PIVEG's purported process was hindered by numerous difficulties. In addition, Dr. Carta concluded that the process observed during the second inspection "deviated significantly from the process previously disclosed in the PIVEG process document."<sup>8</sup> Kemin's team claims it encountered further difficulties in its attempts to quantitatively determine PIVEG's actual process when it noted inconsistent pressure readouts on the reactor as compared to the control room, and inconsistent reactor weights observed in the control room as compared to the amount of material represented to have been added to the reactor. PIVEG was unable to confirm whether the pressure gauges or scales were ever calibrated for accuracy.

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<sup>7</sup> Specifically, the conversion of esterified lutein to its nonesterified form.

<sup>8</sup> Specifically, deviations were noted in the first, third, fourth, and fifth steps of PIVEG's purported process. The importance of these difference, if any, will be discussed in the analysis section along with any explanation provided by PIVEG.

Also identified in the second inspection was a "mystery vessel", referred to as T-29 by PIVEG. This vessel is connected to the reactor and is used to take material from or put material into the reactor.<sup>9</sup> While the saponification process was being demonstrated, a pump connecting this vessel to the reactor was activated. While Mr. Espinoza claimed at the time this was independent of the process being observed, Kemin asserts that the activation of the pump, based on the function of the mystery vessel later learned by Kemin, did have some effect on the process whether it was adding or removing material from the reactor.

During the second inspection, production samples were collected by Kemin during certain process steps and were sent to independent third-party laboratories for analysis. Specifically, selected samples were provided to Craft Technologies, Inc., to determine the amount of purified lutein in the specified sample and the amount of saponification; to Galbraith Laboratories, Inc., to determine the amounts of sodium and potassium salts present as well as to determine the amounts of other specified solvents; and to Dr. Carta, who analyzed micrographs that were obtained after other selected samples were inspected under a microscope. The testing results from the second inspection showed the

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<sup>9</sup> This was learned by Kemin during later depositions of Mr. Espinoza and Mr. Richardson, long after the second inspection was concluded.

presence of undisclosed solvents<sup>10</sup> and an undisclosed recrystallization step,<sup>11</sup> which results were inconsistent with the PIVEG process document.

Finally, PIVEG changed its process following the second inspection. This was confirmed by counsel for PIVEG in a January 26, 2004, letter to Kemin. Both Mr. Espinoza and Mr. Pichardo indicated in their depositions that this change was undertaken within days of the second inspection. As a result of this change, PIVEG no longer uses propylene glycol anywhere in the current process. Again, based on specific instructions, there is no documentation or record evidence of this change. In fact, only Mr. Espinoza and Mr. Pichardo know PIVEG's actual process for producing purified lutein.

#### ANALYSIS

Kemin moves the Court to establish a presumption pursuant to 35 U.S.C. § 295 that PIVEG's purified lutein product is made by Kemin's patented process as claimed by

<sup>10</sup> Specifically, upon his review of the solvent analysis performed by Galbraith Labs, Dr. Carta concluded the samples contained substantial concentrations of hexane and methylene chloride. According to Kemin, hexane, while included as an additive in the PIVEG process document, should not have been in the selected samples because Mr. Pichardo testified this step was not observed or performed during the second inspection, and in fact normally took place in a separate tank. In addition, Mr. Pichardo testified there is no methylene chloride in PIVEG's process. Dr. Carta notes these solvents cannot be created in the process and therefore must have been added during the process.

In addition, Dr. Carta determined a preponderance of potassium over sodium was used in the second inspection runs, inconsistent with the ratios for potassium and sodium hydroxide specified in the PIVEG process document. Mr. Pichardo later confirmed the specified ratios in the process document was an error.

<sup>11</sup> Dr. Carta concluded that the increase in crystal size of certain observed samples "would require a recrystallization step" that was neither observed nor contained in the PIVEG process document.

the '564 patent.<sup>12</sup> In support of this motion, Kemin asserts that (1) a substantial likelihood exists that PIVEG's purified lutein product was made by the patented process, and (2) Kemin has made reasonable efforts to determine PIVEG's actual process for producing lutein, and said efforts have been unsuccessful.

#### **A. Legal Standard for Application of the Section 295 Presumption**

Congress amended the patent statutes in 1988 to prohibit the unauthorized importation, sale, or use of an infringing product manufactured abroad. See Pfizer v. F & S Alloys & Minerals Corp., 856 F. Supp. 808, 810 (S.D.N.Y. 1994). Specifically, 35 U.S.C. section 271 states, in relevant part:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the patented product occurs during the term of such process patent.

35 U.S.C. § 271(g).

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<sup>12</sup> PIVEG states that this is the second time Kemin has requested this Court impose the burden-shifting presumption in section 295. The first time was in connection with Kemin's motion for preliminary injunction, filed July 2002. The Court denied Kemin's motion to shift the burden at that time, finding Kemin had not made reasonable efforts to determine PIVEG's process and that Kemin could not prove a substantial likelihood of infringement. Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V., 240 F. Supp. 2d 963, 977-78 (S.D. Iowa 2003). The Court notes that its prior order was based on a different set of facts than the present motion, so any inference that the aforementioned finding should affect the outcome of the present motion is misplaced. The present motion to apply section 295 will be analyzed by the Court on its merits at this stage of the litigation.

Congress set out the burden of proof for claims brought under this section in a companion statute. See Pfizer, 856 F. Supp. at 810. This companion statute provides the following:

In actions alleging infringement of a process patent based on the importation, sale, offer for sale, or use of a product which is made from a process patented in the United States, if the court finds –

- (1) that a substantial likelihood exists that the product was made by the patented process, and
- (2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine,

the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.

35 U.S.C. § 295. Therefore, for the section 295 presumption to apply, the statute requires that the party seeking the presumption establish, by a preponderance of the evidence, a substantial likelihood the allegedly offending product was made by the patented process, and the movant has made a reasonable yet unsuccessful effort to determine the actual process. Id.; Pfizer, 856 F. Supp. at 810.

#### **B. Substantial Likelihood of Infringement**

Kemin asserts that, despite the lack of reliable information regarding PIVEG's process for producing purified lutein, sufficient information is available to establish a

substantial likelihood of infringement of claim 1 of the '564 patent<sup>13</sup> by PIVEG's process, at least under the doctrine of equivalents.

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<sup>13</sup> In its order on claim construction, the Court construed *inter alia* claim 1 of the '564 patent. In that order, the Court held the following:

[O]ne of ordinary skill in the art would understand the process described in claim 1 of the '564 patent to comprise the following steps: The saponification mixture is prepared by mixing the plant oleoresin with propylene glycol and an aqueous alkali solution of sodium or potassium hydroxide, collectively forming a fine dispersion (steps a and b). The saponification mixture contains 35-40% oleoresin, 30-45% propylene glycol, 5-10% alkali, and 7-15% water. The saponification mixture is maintained at a temperature ranging from about 60 to 80°C. This serves to saponify the xanthophyll diesters and form xanthophyll crystals (step c). Thereafter, approximately 3-19 volumes of water (per unit volume of the saponification mixture) are added at a temperature between about 60 and 80°C and mixed to form a diluted mixture containing xanthophyll crystals (steps d and e). Finally, the xanthophyll crystals are collected from the diluted mixture (step f). These are then washed and dried (step g). The "saponification reaction mixture" consists of four constituents at specified weight percentages in a ratio of about 4:4:1:1. The weight percentage of oleoresin and propylene glycol should together make up about 75 percent of the "saponification reaction mixture."

The Court also finds steps a and b need not be performed sequentially, as one of ordinary skill in the art would have understood these steps could be performed in a modified order and still achieve the same final result. The scope of the claim also covers processes that consist of all the listed steps along with other additional steps as long as the additional steps do not meaningfully change the process described in the claim. In addition, while the use of propylene glycol is necessary and cannot be substituted for, the claim does not exclude the use of any and all additional solvents as part of the process. The Court also construes the claim as allowing for the use of either sodium hydroxide or potassium hydroxide or some combination of both.

Kemin I, 301 F. Supp. 2d at 995-96.

Infringement under the doctrine of equivalents requires that the accused process perform substantially the same function in substantially the same way to produce substantially the same result as the process claimed. See Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950) (citations omitted). This doctrine prevents patent holders from being deprived of the benefit of their patent by competitors who appropriate the essence of an invention while avoiding the literal language of the patent claims. See London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir. 1991).

Kemin asserts that PIVEG's process infringes every element of the '564 patent under the doctrine of equivalents. Kemin proceeds to detail the alleged infringement of the '564 patent under the doctrine of equivalents by breaking up each of the patent steps into the "function", "way", and "result" and comparing them to PIVEG's process. In so doing, Kemin relies on the process disclosed in PIVEG's process document, the process demonstrated in the second inspection, and Dr. Carta's expert analysis.<sup>14</sup> Kemin

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<sup>14</sup> One of PIVEG's contentions is essentially that Kemin cannot show a likelihood of success if it has to rely on the discovery it later argues is insufficient. In other words, PIVEG argues that "Kemin's allegation that it is unable to determine PIVEG's process is belied by its claim that its discovery indicates a substantial likelihood that PIVEG infringes claim 1 of the '564 patent." Kemin necessarily relies on the discovery it has done in compiling the argument that PIVEG's process infringes Kemin's '564 patent under the doctrine of equivalents. PIVEG contends this illustrates the level of intimacy Kemin has been allowed to determine PIVEG's process, and it is disingenuous for Kemin to claim it has been denied adequate discovery (and therefore cannot determine PIVEG's process) while simultaneously arguing it has been provided sufficient discovery to make and support an argument of substantial likelihood of infringement. This interpretation of section 295 would seem to render the section meaningless, especially under the circumstances of the present case. The Court finds under the facts of this case that Kemin's use of its discovery materials to prove a substantial likelihood of infringement can be

concludes that PIVEG's process does infringe on Kemin's '564 patent, thereby meeting the requirement that there be a substantial likelihood of infringement for the section 295 presumption to apply.

### **1. Infringement Under the Doctrine of Equivalents: Function-Way-Result Test**

#### **a. Steps (a) and (b) of Claim 1 of the '564 Patent**

Steps (a) and (b)<sup>15</sup> of claim 1 require the preparation of saponification mixture by mixing a plant oleoresin with propylene glycol and an aqueous alkali solution of sodium or potassium hydroxide, collectively forming a fine dispersion. This saponification mixture contains 35-40% oleoresin, 30-45% propylene glycol, 5-10% alkali, and 7-15% water.

The *function* of steps (a) and (b) is to begin the process of saponifying the plant oleoresin by preparing a saponification reaction mixture to effectively convert a xanthophyll diester-containing oleoresin to xanthophyll crystals. PIVEG's process document discloses the preparation of an effective saponification reaction mixture of a marigold oleoresin in the first two steps of PIVEG's process. In addition, Dr. Carta concluded that a comparison of the laboratory analysis performed on samples taken from

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reconciled with Kemin's argument that such discovery was deficient and did not allow it to determine PIVEG's actual process.

<sup>15</sup> Again, the Court reiterates its finding on claim construction that "the order of the steps of the '564 patent process need not be performed sequentially as listed in Claim 1." Kemin I, 301 F. Supp. 2d at 993. This statement applies specifically to steps (a) and (b). Id. at 996.

the second inspection, specifically, samples 1 and 5, indicated that marigold oleoresin was saponified in PIVEG's demonstrated process. This conclusion was based on the dramatic increase in measurements of lutein saponification.

The *way* steps (a) and (b) are accomplished is by mixing a plant oleoresin with an aqueous alkali solution and propylene glycol, and by heating the mixture. The combined mixture is 35-40% oleoresin, 30-45% propylene glycol, 5-10% alkali, and 7-15% water. PIVEG's process document discloses that in the first two steps, the marigold oleoresin is mixed with propylene glycol and potassium/sodium hydroxide mixture while heating. In his report, Dr. Carta noted the addition of propylene glycol and the potassium/sodium hydroxide mixture while heating was observed during the process demonstration and subsequently confirmed by the laboratory analysis. Dr. Carta further noted that "reliable information regarding the mixture component amounts and temperatures used in the PIVEG process are not available, given the numerous process discrepancies described previously." Nonetheless, Dr. Carta opines that "sufficient quantities and appropriate temperatures were employed, given the resulting lutein crystals."

The *result* of steps (a) and (b) is a saponification mixture that can be further processed in step (c). As stated above, PIVEG's process document discloses the preparation of an effective saponification reaction mixture of a marigold oleoresin in the first two steps of PIVEG's process. Moreover, Dr. Carta noted that laboratory analysis performed on a sample taken at this step indicates the presence of free form lutein crystals.

**b. Step (c) of Claim 1 of the '564 Patent**

Step (c) of claim 1 requires that the saponification reaction mixture be maintained at a temperature between about 65 and about 80°C to saponify the xanthophyll diesters and form xanthophyll crystals.

The *function* of this step is to provide sufficient time for the saponification reaction to occur further and form xanthophyll crystals. PIVEG's process document describes that the saponification takes place for 40 minutes. According to Dr. Carta, the laboratory analysis performed on a sample from this step of the observed process indicated that lutein saponification was "97.9% after approximately 50 minutes following addition of the alkali mixture and propylene glycol to the marigold oleoresin."<sup>16</sup>

The *way* step (c) is accomplished is by maintaining the saponification mixture at a temperature between about 65 and about 80°C. PIVEG's process document describes that the saponification takes place at temperatures from 80 to 110°C. According to Dr. Carta, "while the use of a higher temperature may result in a faster reaction, the PIVEG process effectively operates in the same way as step (c), given that the PIVEG process maintains the saponification mixture at a temperature and for a period of time sufficient to saponify the xanthophyll esters and form xanthophyll crystals, resulting in a high

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<sup>16</sup> PIVEG charges Kemin with blind reliance on this statement from Dr. Carta. PIVEG claims it is unsupportable by contending there is no record of a sample taken at this time. PIVEG claims there were samples taken after 40 minutes, but these were before the addition of propylene glycol. Kemin counters by pointing to exhibits in the record to support Dr. Carta's statement. Thus, Kemin has provided the Court with a sufficient basis to rely on Dr. Carta's statement on this point.

degree of saponification." Thus, it is Dr. Carta's opinion that PIVEG's process essentially produces purified lutein the same way as step (c).

The *result* of step (c) is a saponified plant oleoresin product containing xanthophyll crystals. As stated above, PIVEG's process document discloses the saponification of a marigold oleoresin in the first two steps of PIVEG's process. Moreover, Dr. Carta confirmed that laboratory analysis of a sample from the observed process for this step indicated "the presence of free form lutein crystals."

**c. Steps (d) and (e) of Claim 1 of the '564 Patent**

Steps (d) and (e) of claim 1 require the addition of about 3 to 19 volumes of water per unit volume of saponification mixture at a temperature between about 60 and about 80°C, and mixing to form a homogeneous diluted mixture containing xanthophyll crystals.

The *function* of steps (d) and (e) is to dilute the saponified oleoresin mixture to dissolve saponified fatty acids and other water-soluble materials and to disperse the xanthophyll crystals formed in steps (a) through (c). PIVEG's process document discloses the addition of water at the end of the saponification, thereby allowing the dissolution of saponified fatty acids and the dispersion of xanthophyll crystals. As indicated by Dr. Carta in his report, the laboratory analyses performed on a sample from this step indicated that "this is a diluted homogeneous suspension of xanthophyll crystals."

The *way* steps (d) and (e) are accomplished is by adding about 3 to about 19 volumes of water per unit volume of saponification mixture at a temperature between about 60 and about 80°C. PIVEG's process document describes the addition of

"approximately 934 kg of water at 50°C." According to Dr. Carta, "this corresponds to a volume ration of approximately 3.5 volumes of water per unit volume of saponification mixture." Dr. Carta further opined that "although the temperature of the water added is slightly lower than the range appearing in claim 1, PIVEG's disclosed process uses warm water as in the preferred embodiment of the '564 patent." Further, "the '564 patent teaches that if cold water is used, additional heat is provided to the diluted reaction mixture to maintain a temperature range of about 60 to about 80°C, preferably about 70°C." According to Dr. Carta, "PIVEG's observed process following addition of water to the saponification mixture resulted in temperatures between about 107°C, initially, and about 61°C at the end of the water addition step, with the temperature of the diluted saponification mixture remaining between about 84° and about 61°C for the vast majority of the water addition step." As a result, Dr. Carta concluded that "the use of a slightly lower water feed temperature has no practical effect . . . and thus, PIVEG's disclosed process effectively operates in the same way as steps (d) and (e)."

The *result* of steps (d) and (e) is a diluted saponification mixture containing xanthophyll crystals. According to Dr. Carta, the laboratory analysis performed on a sample from that step indicates that "the result of PIVEG's observed process is a diluted saponification mixture containing xanthophyll crystals."

**d. Steps (f) and (g) of Claim 1 of the '564 Patent**

Steps (f) and (g) of claim 1 require that the xanthophyll crystals be collected from the diluted mixture (step f) and then washed and dried (step g).

The *function* of steps (f) and (g) is to separate xanthophyll crystals from the remaining components in the diluted saponification mixture. PIVEG's disclosed process describes the separation of xanthophyll crystals from other components of the diluted saponification mixture (isolation step), washing (removal of gums step and removal of other contaminants step), followed by drying to produce a powder.

The *way* steps (f) and (g) are accomplished is by collecting, washing, and then drying. PIVEG's disclosed process also describes the collecting, washing, and drying of xanthophyll crystals. Moreover, as Dr. Carta noted, "PIVEG's observed process includes the steps of collecting xanthophyll crystals and washing them to separate soluble impurities." In addition, "although a drying step was not demonstrated by PIVEG during the second inspection, it was described by PIVEG during the first inspection including a demonstration of the equipment that PIVEG uses to dry its lutein powder product."

The *result* of steps (f) and (g) is dried xanthophyll crystals. PIVEG's process document is subtitled "Isolation and purification of xanthophyll crystals". In addition, the document itself discloses that their lutein powder product is produced by drying.

Based on this analysis, Kemin asserts that each and every element of claim 1 of the '564 patent is found in the PIVEG process whether literally or equivalently. The conclusions about the actual PIVEG process are based upon the process disclosed by the PIVEG process document, the subsequent demonstration at the second inspection, and the independent laboratory analyses in conjunction with Dr. Carta's expert analysis.

As such, Kemin contends it has established a substantial likelihood that PIVEG's process for producing purified lutein infringes the '564 patent.

## **2. Infringement Under the Doctrine of Equivalents: Equivalency**

PIVEG acknowledges that Kemin correctly recites the function-way-result test used in a doctrine of equivalents analysis but contends that Kemin's argument under the doctrine is inherently flawed as Kemin is unable to satisfy any part of the three-part test. Specifically, PIVEG contends Kemin's argument has two flaws: (1) Kemin incorrectly argues that steps (a) and (b) of the '564 patent are equivalent to the combined saponification and emulsification steps of the PIVEG process; and (2) Kemin ignores limitations in claim 1 and the evidence that PIVEG's process has no equivalent limitations.

PIVEG's first argument is based principally on the contention the saponification step in PIVEG's process does not involve propylene glycol (or equivalent element) in any amount, but instead includes other reactants at very different ratios and at higher temperatures than the process protected by the '564 patent. PIVEG does use propylene glycol in its process, but only to emulsify the already saponified lutein crystals. Accordingly, PIVEG contends its saponification reaction is achieved in a far different *way* and that propylene glycol in PIVEG's process has a far different *function* than the '564 patent process. PIVEG accuses Kemin of ignoring this difference.

PIVEG's second argument basically claims Kemin fails to prove that the PIVEG process is substantially equivalent *to each and every* element of claim 1 of the '564 patent as required for infringement to lie. See Dynacore Holdings Corp. v. U.S. Philips

Corp., 363 F.3d 1263, 1273 (Fed. Cir. 2004). Again, PIVEG contends that it does not use propylene glycol in its saponification reaction, making it impossible for Kemin to show a substantial equivalence to the '564 process. PIVEG also points to the different ways the two processes remove contaminants and obtain the lutein crystals. In addition, PIVEG states its use of phase separations based on polarity and acidity is a vastly different way (and function) to remove impurities in the lutein mixture than Kemin's technique to collect, wash, and dry the crystals.

Finally, PIVEG contends that Kemin has only offered conclusory proof or omissions in asserting substantial equivalence. PIVEG points to the difference in temperature and use of propylene glycol in the '564 patent's saponification reaction as compared to PIVEG's process. PIVEG also indicates the saponified and emulsified material from its process is a semi-solid paste, much different from the material at the same stage in the '564 process. In addition, PIVEG claims Kemin has made no showing of the substantial equivalence on the final step of the process as Dr. Carta provides no observation of crystals in the final product. PIVEG also claims the information available conclusively establishes noninfringement and that for the foregoing reasons, Kemin is unable to establish a substantial likelihood of infringement.

However, to obtain a presumption, section 295 requires that Kemin establish a *substantial likelihood* that the allegedly offending process infringes the protected process. In other words, Kemin need not *prove* infringement. Kemin adequately considers each step of the '564 patent process, a determination as to the function of that

step, the way in which the step is performed, and the result of each step, supported by the scientific observations of its expert, Dr. Carta, which are based on two inspections and a battery of comprehensive tests performed by two independent third-party labs. On the other hand, PIVEG bases its arguments on the uncorroborated process document and fails to cite any specific scientific evidence to substantiate its assertions or rely upon any of its experts to support its conclusions.<sup>17</sup>

The Court finds Kemin has shown a substantial likelihood that PIVEG's *actual* process infringes on the '564 patent process, at least under the doctrine of equivalents. The Court emphasizes that it is not finding infringement as a matter of law. The Court bases this determination on the information available on PIVEG's process, including the PIVEG process document, the observations from the first and second inspections, the results of the sample tests performed by independent third-party laboratories, and the observations and conclusions of Kemin's experts. It may very well be that PIVEG's actual process does not infringe on claim 1 of the '564 patent, but PIVEG must do more than rely on the base assertions made here. Therefore, the Court finds Kemin has met the first requirement under section 295 for the burden-shifting presumption to apply.

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<sup>17</sup> Kemin notes that only one of the three saponification runs obtained the results upon which PIVEG relies, and this run was conducted on the second day of the second inspection when no control samples were available for Kemin to authenticate the results. Kemin avers this indicates propylene glycol is required in PIVEG's process. In support, Kemin cites Dr. Carta's conclusion that the only reason for the poor saponification of the initial runs was the fact that propylene glycol was not used.

### C. Reasonable Effort to Determine Actual Process

Kemin contends that it has exhausted all reasonable means to discover PIVEG's actual process for producing purified lutein prior to the close of discovery. It has sought and received through written requests all documents related to PIVEG's lutein purification process, made two facility inspections along with associated testing, and conducted deposition of Messrs. Espinoza and Pichardo, the only two individuals with knowledge of the entire process employed by PIVEG. Kemin asserts that despite its efforts, it is unable to determine PIVEG's actual process. PIVEG disagrees, stating it has fully complied with all discovery efforts made by Kemin and that Kemin's lack of understanding does not meet the requirements for application of the section 295 presumption.

The parties rely on different cases in supporting their contentions. PIVEG relies on Nutrinova v. International Trade Commission, a case where the Federal Circuit determined the section 295 presumption did not apply. See Nutrinova v. Int'l Trade Comm'n, 224 F.3d 1356 (Fed. Cir. 2000). In that case, plaintiff filed an infringement action against a Chinese corporation, conducted a plant inspection (reluctantly agreed to by defendant), and tested samples, which results showed different by-products than expected. Id. at 1358-59. The court noted that plaintiff's testing indicated defendant likely practiced one of the two well-known noninfringing methods to produce the product. Id. at 1358. The plaintiff moved for a section 295 presumption which was denied by the court based upon the court's determination that plaintiff received

sufficient discovery to be able to determine the defendant's process, thereby failing to meet the second prong of the section 295 requirements for application. Id. at 1360.

Meanwhile, Kemin relies on Pfizer Inc. v. F & S Alloys and Minerals Corporation, in which the court determined the section 295 presumption did apply as plaintiff was provided with little discovery and thus was unable to determine defendant's actual process. Pfizer, 856 F. Supp. at 810-12. Plaintiff was provided an expert's report that had reliability and admissibility issues because it was based on hearsay. Id. at 811-12. Plaintiff's expert then opined, using the hearsay report and other information gathered by plaintiff from a visit to defendant's factory, that the process as disclosed was not the actual process. Id. at 812. The expert further posits that there was a high likelihood of infringement because to yield the final product, defendant's process would have to use the reactions covered by plaintiff's patent. Id. The court then found plaintiff met the two requirements of section 295 and therefore applied the burden-shifting presumption. Id. at 815-16.

The present case seems to fall between these two cases. Here, there was discovery obtained, though Kemin contends it was inconsistent and insufficient to allow a reasonable person to discover PIVEG's actual process for purifying lutein. The following section discusses Kemin's discovery as well as both parties' respective contentions on the reasonableness of the discovery. The core issue is whether Kemin's reasonable efforts in conducting discovery would lead to a determination of PIVEG's actual process.

## **1. Kemin's Discovery**

As noted, Kemin has been able to conduct and collect discovery of at least three types: document evidence, site inspections and sample testing, and depositions. PIVEG reiterates that it has fully complied with all of the discovery requests made by Kemin and has accommodated Kemin in its attempts to discover PIVEG's actual process for purifying lutein.

### **a. Document Evidence**

Kemin originally sought to ascertain PIVEG's process through standard written discovery requests. These requests resulted in the two-page process document from PIVEG. This document was prepared by PIVEG at the behest of its attorneys for purposes of this litigation and apparently is the only documentation of PIVEG's purported process. According to Kemin, this document is not consistent with or representative of the process demonstrated at either of the two site inspections. In addition, Kemin points out that PIVEG has designed and operates its production facility without any documentation or records.

PIVEG states that it has not withheld any documents from Kemin. To the contrary, Kemin has received all documents it has requested that are in PIVEG's possession. PIVEG justifies the lack of documentation by stating it has, as a matter of policy, carefully kept paper records that would reveal its process to a bare minimum in order to protect its process trade secret. Prior to this suit, there was no written record of the process anywhere.

The Court finds that section 295 is about substance and not just form. It is intended to address any situation where a party is unable to discover a foreign defendant's process through reasonable discovery, regardless of whether the other side has refused to respond to a specific document request. Failure to produce design and production documents in the litigation or failure to create such normal and routine documents in the first place creates the same result in terms of a challenger's ability to discover and litigate a process claim. In the present case, additional document requests would be pointless, especially considering PIVEG's admission that no further documentation exists and the current altered process is now completed without any documentation whatsoever. Moreover, there are no other reasonable avenues of discovery that would provide the results Kemin seeks.

In addition, PIVEG's argument that it has provided Kemin with all documents and information concerning its purported process for purifying lutein that would be commensurate with that provided by a domestic corporation fails. Indeed, if PIVEG were a domestic corporation, compliance with U.S. regulations would require PIVEG maintain a multitude of documents related to its process.<sup>18</sup> Thus, PIVEG has, through a

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<sup>18</sup> U.S. regulations would include, but would not be limited to, the following record-keeping requirements: Documents concerning general processes and controls, including standard operating procedures for quality control, quality assurance, and sampling, see 21 C.F.R. § 110.80; Documents regarding Good Manufacturing Practices ("GMP"), including a GMP plan and GMP file, see 21 C.F.R. § 110.5; Standard operating procedures for product recalls, complaint tracking, non-conforming products, batch rejections, see 21 C.F.R. § 110.80; User manuals for all equipment, see 21 C.F.R. § 110.40(a); and Documents concerning preventative maintenance, including equipment calibration and equipment maintenance, see 21 C.F.R. § 110.40(a), (f).

strategic decision apparently allowed in Mexico, acted to preclude Kemin from obtaining the type of written discovery Kemin would be able to discover if PIVEG were a domestic corporation.

**b. Site Inspections and Sample Testing**

Kemin undertook two separate inspections of PIVEG's lutein purification process, the second precipitated by the fact that much of PIVEG's process was nonoperational at the first inspection. In conjunction with the second inspection, Kemin also undertook a comprehensive effort to obtain representative samples from selected process steps for submission to third-party laboratories for analysis. According to Kemin, the second inspection and the associated testing efforts identified numerous discrepancies between PIVEG's purported process and the process demonstrated during the inspection. Kemin delineates the following as the most significant deviations:

- (1) the omission of multiple steps (e.g., the absence of specified heating steps and the absence of specified repeated hexane wash steps); (2) the use of different potassium and sodium hydroxide ratios than specified; (3) the unexpected appearance of substantial amounts of hexane at intermediate steps inconsistent with the PIVEG process document; (4) the inability or failure of PIVEG personnel to demonstrate specified performance results (e.g., the lack of a specified phase separation following neutralization step); (5) the observance of an increase in crystal size in subsequent process steps consistent with an undisclosed recrystallization step;<sup>19</sup> and (6) the appearance of

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<sup>19</sup> The existence of this "extra" step would not preclude a finding of infringement as claims written in an open-ended format, i.e., those using the term "comprising" (such

substantial amounts of methylene chloride, a chlorinated organic solvent that is not mentioned in the PIVEG process document and whose addition was not demonstrated by the operators or otherwise observed by the inspection team.

In addition to these discrepancies, Kemin claims that the inspection personnel were unable to obtain accurate and reliable information with respect to the process that was actually observed. Specifically, there was no indication that PIVEG undertook any effort to properly calibrate the pressure gauges and weight scales. Kemin contends accurate pressure and weight readings are essential to PIVEG's process and cannot be obtained without properly calibrated instruments. In addition, Kemin personnel observed significant discrepancies between the pressure measurements taken at the reactor and those obtained in the control room, and the reactor weights observed in the control room were not consistent with the weights of materials actually added to the reactor. Consequently, Kemin contends it was left to guess as to which information would be more reliable.

Kemin also contends that PIVEG failed to provide a satisfactory explanation for "the sudden and unexpected activation of a pump during the inspection." Kemin claims this mystery vessel appears to have materially affected the observed process. Despite Mr. Espinoza's comments to the contrary, Kemin contends that the activation of a pump

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as claim 1 of the '564 patent), allow for additional steps or elements. See Dow Chem. Co. v. Sumimoto Chem. Co., 257 F.3d 1364, 1380 (Fed. Cir. 2001) (quoting Amstar Corp. v. Envirotech Corp., 730 F.2d 1476, 1482 (Fed. Cir. 1984) (finding it is a well-established principle that the "mere addition of elements [in the accused product or process] cannot negate infringement")).

connecting the vessel referred to as T-29 indicates material was being removed from or added to the saponification reactor in use during the demonstration of PIVEG's process. Irrespective of which operation was in effect, the activation of the pump would have a direct impact on the material contents of the saponification reactor and the corresponding results of the saponification reaction. Thus, Kemin argues that after the pump was activated, its personnel could no longer be certain as to what the reactor actually contained, despite careful monitoring of the process being demonstrated.

PIVEG points out that Kemin and its experts have visited PIVEG's facilities not once but twice, have videotaped and photographed various activities and equipment, and have observed various parts of PIVEG's automated process, which PIVEG performed manually at Kemin's request and for Kemin's benefit. In addition, Kemin asked for and was allowed to collect and test more than twenty samples from various stages of the process.

As far as any perceived or actual discrepancies, PIVEG points out that its process for purifying lutein takes 10 to 14 days to complete, and that Kemin was aware of this prior to both of its site inspections. The Court itself advised that Kemin should observe PIVEG's entire process, but the parties, and Kemin specifically, agreed to a two-day visit.<sup>20</sup> PIVEG asserts this affected the accuracy of PIVEG's process as PIVEG

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<sup>20</sup> Kemin asserts the second inspection was not conducted in some haphazard manner leading to the myriad of process discrepancies, calling PIVEG's statements on this matter a "gross mischaracterization of the *mutually agreed upon* inspection protocol, which was carefully designed in advance . . . so as to minimize the time, inconvenience and cost to *both* parties."

completed an abbreviated, segmented, out-of-sequence, incomplete, manual demonstration of its otherwise automated process in order to meet Kemin's requests to videotape certain portions of the process and take samples at various stages.<sup>21</sup>

PIVEG also counters Kemin's complaints regarding the ability to observe the process and lack of safety features by noting its facility is "not a tourist attraction" and PIVEG cannot be expected to refurbish its plant for the convenience of litigants. Regardless, these complaints have little to do with the section 295 requirements. PIVEG attempts to attribute the additional runs in the second inspection to mechanical failure and states the additional runs were made for Kemin's benefit. PIVEG further notes Dr. Carta omitted from his report indicia of corroboration of the PIVEG process document<sup>22</sup> and failed to ask about the "mystery vessel" during or after the inspection.<sup>23</sup>

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<sup>21</sup> PIVEG points out the numerous problems it incurred in running the process this way and intimates this was the cause of the noted discrepancies. These problems included breaking the seal on reactor during the process, attempting to run the process manually resulting in operator errors, and having some steps completed prior to Kemin's arrival so Kemin could observe later steps of the process. Kemin notes, however, that PIVEG employees did not report any problems with the "problem runs" until after the saponification results indicated poor saponification in those runs, thus giving no prior indication the process was not operating within the normal range of parameters.

<sup>22</sup> For example, the reactants were weighed in full view and then added together in the reactor in full view to prevent tampering, thereby corroborating step one of PIVEG's process document.

<sup>23</sup> Dr. Carta did, however, ask Mr. Espinoza about the vessel during the inspection and its effect upon being activated but was told it had nothing to do with the process being observed. PIVEG also contends that Kemin did not adequately follow up on this, though the record seems to indicate Kemin sought answers in deposition as to what the "mystery vessel" was and what effect it could have.

PIVEG also notes Kemin's failure to offer a scientific explanation for how the extra solvents, i.e., hexane and methylene chloride, might have been added or seek

Kemin has, however, made two inspections of PIVEG's facilities, collected and submitted multiple samples to independent third-party labs for testing, and deposed the only witnesses who know the actual process on any questions it had. Despite its best efforts, Kemin was left with a host of inconsistent observations, unexplained solvents, and constantly changing representations. Most importantly, it would be difficult to determine PIVEG's actual process based upon the facility inspections and the related testing when compared with PIVEG's process document.

**c. Depositions**

Finally, Kemin deposed both Mr. Espinoza and Mr. Pichardo, apparently the only PIVEG officials with knowledge of the actual process employed by PIVEG in purifying lutein. These individuals were deposed some time after the second inspection took place and the independent third-party lab results were returned to Kemin. Despite questioning these individuals about the noted discrepancies in the demonstrated

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discovery on this point. PIVEG stands by the statement of its official that methylene chloride is not used in its purified lutein process and that perhaps the independent labs contaminated the samples.

Kemin asserts this contention is preposterous. Kemin states that PIVEG conveniently ignores the host of documented inconsistencies between its disclosed process document and the observed process. Specifically, PIVEG does not deal with the observed increase in crystal size in the tested samples or the presence of methylene chloride beyond asserting the lab could be at fault. PIVEG also ignores that it obtained duplicate samples that could be sent for testing but which, curiously, have not. In addition, Kemin notes it tested specifically for methylene chloride, and it would be unlikely that an independent lab would coincidentally contaminate the samples with this solvent amongst the thousands of solvents Kemin could have tested for. Moreover, the increased crystal size could not have been through contamination as the result was independently corroborated in second set of samples observed by Dr. Carta.

process, the process document, and the test results, Kemin still has questions as to the *actual* process PIVEG employs in purifying lutein.

## **2. Reasonableness of Efforts and Ability to Determine Actual Process**

Given the lack of documentation, coupled with a lack of reliable, corroborating information from the two inspections of PIVEG's lutein manufacturing plant, Dr. Carta concluded that "specific, reliable information has not been made available concerning PIVEG's process for producing purified lutein." Dr. Carta specifically noted that "reliable information is not available regarding the respective amounts of process materials utilized in PIVEG's process, nor is reliable information available regarding the specific process conditions, such as the operating temperatures utilized by PIVEG in its process for producing purified lutein." Dr. Carta went on to state it was his opinion that "PIVEG's inability to provide such critical information, coupled with the gross discrepancies and inconsistencies observed, may constitute a conscious intent to mislead and/or conceal their actual process for producing purified lutein."

Kemin argues that it has diligently endeavored to discover PIVEG's actual process for producing lutein and has exhausted all reasonable means to obtain such discovery. Despite its efforts, Kemin contends it "is left with a host of inconsistent observations, unexplained solvents, and constantly changing representations that strongly suggest that Kemin has not – in fact – been given discovery of PIVEG's actual process."

PIVEG states that Kemin was provided with all of the documentation requested, was able to conduct multiple site inspections, observing the PIVEG process on multiple occasions, and deposed PIVEG's employees. According to PIVEG, it has certainly subjected itself to and complied with Kemin's discovery requests as if it were a domestic company. Further, PIVEG points out that Kemin has not identified any discovery it allegedly cannot obtain to determine PIVEG's process, has not moved to compel any allegedly missing or withheld discovery, has not identified any discovery requests or court orders with which PIVEG has not complied, and has not propounded additional requests seeking any allegedly missing or withheld discovery; and, as section 295 is not just a burden-shifting mechanism but "also serves the needs of the court as a mechanism for enforcing its processes and orders," Nutrinova, 224 F.3d at 1360, it is not warranted in the present case because PIVEG has complied with every Court order in this matter.

PIVEG urges the Court to find that "substantial evidence supports . . . [a] finding that a reasonable plaintiff would be able to determine the process used" by PIVEG. Nutrinova, 224 F.3d at 1360; see also Novo Nordisk v. Genentech, Inc., 77 F.3d 1364, 1368 n.6 (Fed. Cir. 1996) (finding "[s]ection 295 is inapplicable in the present case, *inter alia*, because [plaintiff] was able to determine the [defendant's] process"). In so urging, PIVEG claims the present case is more akin to Nutrinova, where the Court denied application of section 295, than Pfizer, where the court did apply the presumption.

Ultimately, section 295 only requires that Kemin make a *reasonable effort* to determine PIVEG's actual process, and not the narrow application that PIVEG

proposes, and the Court finds that Kemin has made just such an effort. Kemin has followed all of the avenues of discovery likely to uncover the PIVEG process, including written discovery requests, facility inspections, first-hand observation of the process, independent testing of process samples, the use of experts, and depositions of PIVEG officials. The Court notes that while PIVEG has complied with all of Kemin's requests, Kemin has still been unable to discover PIVEG's actual process. The results of Kemin's discovery have produced contradictions, errors, and discrepancies. The type of documentation typically available from a domestic company would provide objective bases against which to test the subjective arguments offered by PIVEG, and the essential fact is that such documentation is not available because of the strategic decisions of PIVEG. Thus, the Court finds Kemin has fulfilled the second requirement for application of the section 295 presumption.

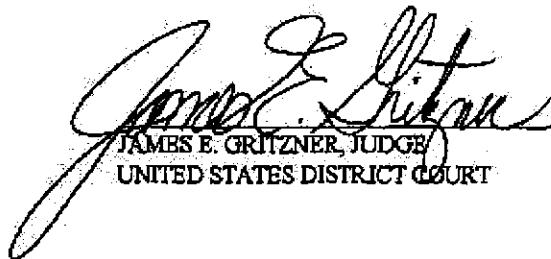
## CONCLUSION

Section 295 was enacted to allow process patent holders to effectively enforce their patent rights against foreign defendants that would deny them adequate discovery of their allegedly infringing processes. The Court finds the present situation is one of the dangers that Congress intended to protect against when enacting this statute. Kemin finds itself in the situation that despite making reasonable efforts, it has not been able to discover PIVEG's *actual* process through discovery. In addition, Kemin has shown a substantial likelihood of infringement under the doctrine of equivalents, thereby making section 295 applicable in the present case. Accordingly, the Court hereby grants

Plaintiff's Motion to Apply 35 U.S.C. § 295 (Clerk's No. 171). For purposes of trial, this holding shifts the burden to PIVEG to prove its actual process for not infringing claim 1 of the '564 patent held by Kemin.

**IT IS SO ORDERED.**

Dated this 27th day of August, 2004.



JAMES E. GRITZNER, JUDGE  
UNITED STATES DISTRICT COURT